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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dakai Liu and Elazar Rabbani)
Serial No. 09/046,833)
Filed: March 24, 1998)
Title: VECTORS, VIRAL VECTORS AND)
PACKAGING CELL LINES FOR)
PROPAGATING SAME)

Group Art Unit: 1636

Examiner: David Guzo

527 Madison Avenue, 9th Floor
New York, New York 10022
October 30, 2003

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P.O. Box 1450
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INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§1.56 & 1.971.98

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.971.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following fifty-eight (58) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

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Enz-56(D4)

Dakai Liu and Elazar R. Bani

Serial No.: 09/046,833

Filed: March 24, 1998

Page 2 [Information Disclosure Statement

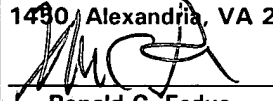
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EXPRESS MAIL CERTIFICATE

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I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Ronald C. Fedus
Reg. Exhibit 32,567

OCT 30 2003

Date

1. Morgenstern, J.P. et al, "Choice and Manipulation of Retroviral Vectors," Gene Transfer and Expression Protocols. Methods in Molecular Biology, Vol. 7:181-193; (1991), Murray, E.J., Ed., The Humana Press, New Jersey [EXHIBIT 1]
2. Anderson, W.F, "Human Gene Therapy," Science 256:808-813 (1992) [EXHIBIT 2]
3. Mulligan, R.C, "The Basic Science of Gene Therapy," Science 260:926-932 (1993) [EXHIBIT 3]
4. Smith, A.E, "Viral Vectors in Gene Therapy," Ann Rev. Microbiol, 49:807-38 (1995) [EXHIBIT 4]
5. Muzyczka, N, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," Current Topics in Microbiology and Immunology 158:97-129 (1992) [EXHIBIT 5]
6. Kotin, R.M, "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," Human Gene Therapy 5:793-801 (1994) [EXHIBIT 6]
7. Berkner, K.L, Curr. Top. Microbiol. Immunol. 158:39-66 (1992) [EXHIBIT 7]
8. Emerman, M et al., "Genes with Promoters in Retrovirus Vectors Can Be Independently Suppressed by an Epigenetic Mechanism," Cell 39:459-467 (1984) [EXHIBIT 8]
9. Emerman, M et al., "Quantitative Analysis of Gene Suppression in Integrated Retrovirus Vectors," Molecular and Cellular Biology 6(1):792-800 (1986) [EXHIBIT 9]
10. Emerman, M et al., Nucleic Acids Res. 14:9381-9396 (1986)[EXHIBIT 10]
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12. Hawley, R.G. et al., "Handicapped retroviral vectors efficiently transduce foreign genes into hematopoietic stem cells," Proc. Natl. Acad. Sci. USA 84: 2406-2410 (1987) [EXHIBIT 12]
13. Yee, J.K et al., "Gene expression from transcriptionally disabled retroviral vectors," Proc. Natl. Acad. Sci. USA 84:5197-5201 (1987) [EXHIBIT 13]
14. Dougherty, J.P and Temin H.M., "A promoterless retroviral vector indicates that there are sequences in U3 required for 3' RNA processing," Proc. Natl. Acad. Sci. USA 84:1197-1201 (1987) [EXHIBIT 14]
15. Whitcomb, J.M and Hughes, S.H., "Retroviral Reverse Transcription and integration: Progress and Problems" Ann. Rev. Cell Biol. 8:275-306 (1992) [EXHIBIT 15]
16. Jaenisch, R et al., "Germline Integration of Moloney Murine Leukemia Virus at the Mov13 Locus Leads to Recessive Lethal Mutation and Early Embryonic Death," Cell 32:209-216 (1983) [EXHIBIT 16]
17. Fung, Y.T. et al., "On the mechanism of retrovirus-induced avian lymphoid leucosis: Deletion and integration of the proviruses," Proc. Natl. Acad. Sci. USA 78(6):3418-3422 (1981) [EXHIBIT 17]
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32. Maddon, P.J et al., Cell 47:333-348 (1986) [EXHIBIT 32]
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The first forty-seven (47) foregoing references (numbers 1-47) were cited in the specification of the instant application. Reference 48 was cited by the Examiner on Form PTO 892 in connection with an Office Action issued 09/28/99 in connection with the instant application. References 49 and 50 recently came to the attention of the instant application's assignee. References 51, 52 and 53 were cited in the International Search Report (PCT/US98/05725, dated July 14, 1998). References 54 through 58 were cited in the European Search Report (EP98915153, dated April 15, 2003).

A completed Form PTO-1449 listing the 58 above-submitted documents is also attached hereto as Exhibit 59.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

Enz-56(D4)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dakai Liu and Elazar Rabbani

Serial No. 09/046,833

Group Art Unit: 1636

Filed: March 24, 1998

Examiner: David Guzo

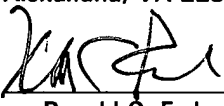
Title: VECTORS, VIRAL VECTORS AND PACKAGING CELL LINES FOR PROPOGATING
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TRANSMITTAL
INFORMATION DISCLOSURE STATEMENT

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Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

EXPRESS MAIL CERTIFICATE	
"Express Mail" Label No.:	<u>EL492433417US</u>
Deposit Date:	<u>October 30, 2003</u>
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
 Ronald C. Fedus Reg. Exhibit 32,567	<u>OCT 30 2003</u> Date

Enz-56(D4)

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. _____, filed _____.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
 - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
 - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
 - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
 - ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.

☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-56(D4). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - b. the attached petition requesting consideration of this Information Disclosure Statement; and
 - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
 - b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
 - c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Enz-56(D4)

10. [] A check in the amount of \$180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

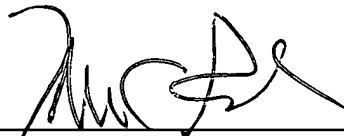
[X] Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. **56(D4)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

[x] The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: October 30, 2003

By:



Ronald C. Fedus

Registration No. 32,567

Mailing Address:

ENZO LIFE SCIENCES, INC.
c/o Enzo Biochem, Inc.
292 Madison Avenue, 9th Floor
New York, New York 10022
Telephone: (212) 583-0100
Telefax: (212) 583-0150

Enz-56(D4)

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

Atty. Docket No.
ENZ-56(D4)

Serial No. 09/046,833

INFORMATION DISCLOSURE CITATION
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Applicants: Dakai Liu and Elazar Rabbani

Filed: March 24, 1998

Group: 1636

U.S. PATENT DOCUMENTS

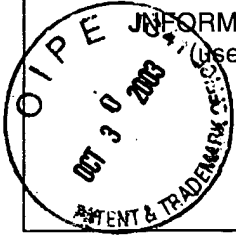
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	5 1 6 6 3 2 0		Wu et al			
	5 6 5 0 3 0 9		Wong-Staal et al.			
	5 2 7 8 0 5 6		Bank et al.			
	6 1 5 6 4 7 9		Kaleko et al			
	5 8 5 6 1 5 2		Wilson et al			

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
W 9 8 3 7 9 1 7					
EP 1 2 8 3 3 2 B1					
EP 7 7 9 3 6 5 A2					

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Morgenstern, J.P. et al, "Choice and Manipulation of Retroviral Vectors," <u>Gene Transfer and Expression Protocols. Methods in Molecular Biology, Vol. 7:181-193; (1991),</u> Murray, E.J., Ed., The Humana Press, New Jersey
	Anderson, W.F, "Human Gene Therapy," <u>Science 256:808-813 (1992)</u>
	Mulligan, R.C, "The Basic Science of Gene Therapy," <u>Science 260:926-932(1993)</u>
	Smith, A.E, "Viral Vectors in Gene Therapy," <u>Ann Rev. Microbiol. 49:807-38(1995)</u>
	Muzyczka, N, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <u>Current Topics in Microbiology and Immunology 158:97-129</u>
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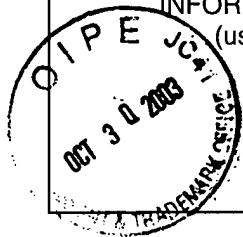
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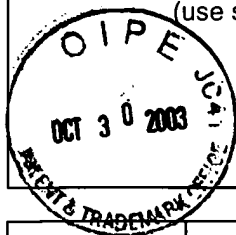
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	Kotin, R.M., "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," <u>Human Gene Therapy</u> 5:793-801 (1994)
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	Yu, S.F et al., "Self-inactivating retroviral vectors designed for transfer of whole genes into mammalian cells," <u>Proc. Natl. Acad. Sci. USA</u> 83:3194-3198 (1986)
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	Yee, J.K et al., "Gene expression from transcriptionally disabled retroviral vectors," <u>Proc. Natl. Acad. Sci. USA</u> 84:5197-5201 (1987)
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Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office	Atty. Docket No. ENZ-56(D4)	Serial No. 09/046,833
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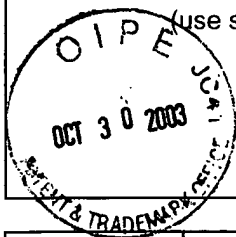
	Dougherty, J.P and Temin H.M., "A promoterless retroviral vector indicates that there are sequences in U3 required for 3' RNA processing," <u>Proc. Natl. Acad. Sci. USA</u> 84:1197-1201 (1987)
	Whitcomb, J.M and Hughes, S.H., "Retroviral Reverse Transcription and integration: Progress and Problems" <u>Ann. Rev. Cell Biol.</u> 8:275-306 (1992)
	Jaenisch, R et al., "Germline Integration of Moloney Murine Leukemia Virus at the Mov13 Locus Leads to Recessive Lethal Mutation and Early Embryonic Death," <u>Cell</u> 32:209-216 (1983)
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INFORMATION DISCLOSURE CITATION (use several sheets if necessary)		
Applicants: Dakai Liu and Elazar Rabbani et al.		
Filed: March 24, 1998		Group: 1636



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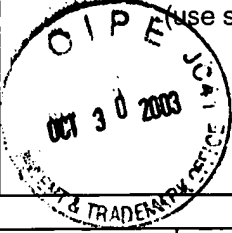
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